UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NORAMCO LLC, Plaintiff, v. DISHMAN USA, INC., Defendant.	C.A. No.: 1:21-cv-01696-WCB

DEFENDANTS' ANSWER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Defendant Dishman USA, Inc. ("Dishman") by its undersigned attorneys, for their Answer to the Second Amended Complaint filed by Noramco LLC ("Noramco") filed April 14, 2022, states as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Dishman denies all allegations in Plaintiffs' Second Amended Complaint except those expressly admitted below.

PARTIES

1. Plaintiff Noramco, LLC, is a Delaware Limited Liability Company with its principal place of business located at 500 Swedes Landing Rd, Wilmington, DE 19801 ("Noramco" or "Plaintiff").

ANSWER: Admitted.

2. Plaintiff is engaged in the business of manufacturing and selling active pharmaceutical ingredients.

ANSWER: Admitted.

3. Defendant Dishman USA, Inc., is a company trading at a business address located at 476 Union Ave, Second Floor, Middlesex, NJ 08446 ("Dishman" or "Defendant").

ANSWER: Admitted.

4. Dishman engages in the manufacture and supply of raw materials and/or intermediates for active pharmaceutical ingredients.

ANSWER: Admitted.

JURISDICTION

5. Plaintiff Noramco hereby claims jurisdiction in the above-captioned action before the United States District Court for the District of Delaware on the grounds of diversity of citizenship of the parties under 28 U.S.C. § 1332(a)(1), to wit, the matter in controversy exceeds the sum or value of $75,000 and the parties are completely diverse from one another.

ANSWER: Denied as to any legal conclusions, otherwise admitted.

6. Defendant has consented to the personal jurisdiction of this District Court pursuant to the forum selection clause of the subject contract at issue, to wit, "12.2 Governing Law. This Agreement shall be governed by, construed and interpreted in accordance with the substantive law of the State of Delaware and venue will exclusively be in the state or federal courts located in the State of Delaware." Supply Agreement, Article 12.

ANSWER: Denied as to any legal conclusions, otherwise admitted.

VENUE

7. Venue and the parties' forum selection clause setting venue in this matter "in the state or federal courts located in the State of Delaware." is proper. Supply Agreement, Article 12.

ANSWER: Denied as to any legal conclusions, otherwise admitted.

FACTS COMMON TO ALL COUNTS

8. On July 1, 2019, Defendant Dishman entered into a Supply Agreement with Plaintiff Noramco (the "Agreement" or the "Supply Agreement"). Exhibit A.

ANSWER: Admitted.

9. The Supply Agreement required Dishman to supply Olivetol (the "Material") to Noramco for the manufacture of active pharmaceutical ingredients ("API") incorporating such Material.

ANSWER: Admitted.

10. Under the terms and conditions of the Supply Agreement, all Material to be supplied under the Agreement shall be manufactured by Dishman at their cGMP Facility located at Lodarival, India, in conformance with Applicable Laws, cGMPs, the Specifications and the Quality Agreement, as those capitalized terms were defined in the Supply Agreement.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

11. Section 1.4 of the Supply Agreement defines "cGMPs" to include both FDA and European Union GMP standards:

> "cGMPs" shall mean current good manufacturing practices, as provided for (and as amended from time to time) in : (a) the Current Good Manufacturing Practice regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act; (b) the European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products), as well as applicable documents developed by the international Conference 6n Harmonization (ICH) Q7 Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical ingredients; (c) the Swissmedic Therapeutic Product Guidelines for authorization and supervision of therapeutic products; and (d) similar requirements of other Regulatory Authorities; subject to any arrangements, additions, or clarifications, and the

respective roles and responsibilities, agreed from time to time between the Parties.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

12. cGMP regulatory requirements are substantially the same in the United States and the European Union.

ANSWER: This allegation is a legal conclusion that does not require a response.

13. Swissmedic adopted ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients ("ICH Q7") as the cGMP standard for the manufacture of Active Pharmaceutical Ingredients on May 1, 20

ANSWER: Defendant is without knowledge to admit or deny this allegation about a third party's practices.

14. US FDA adopted ICH Q7 as the cGMP standard for the manufacture of Active Pharmaceutical Ingredients in the United States on September 1, 2001.

ANSWER: Defendant is without knowledge to admit or deny this allegation about a third party's practices.

15. US and EU regulations reflect that both the are concerned with patient safety.

ANSWER: Defendant is without knowledge to admit or deny this allegation about a third party's practices.

16. Enforcement of what constitutes cGMP non-compliance is essentially the same in the US and EU within the meaning of the Supply Agreement.

ANSWER: Defendant is without knowledge to admit or deny this allegation about a third party's practices.

17. The Parties defined "cGMPs" to include ICH Q7, among other standards.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

18. Section 10.2 of the Supply Agreement provides that:

> "Section 10.2.1 Material. All Material supplied hereunder shall (a) comply with all Applicable Laws and the Quality Agreement[1] and meet all Specifications and cGMP's [current good manufacturing practices], and (b) Dishman shall perform and document all manufacturing and supply activities contemplated herein compliance with all Applicable Laws."
>
> "Section 10.2.2 Facilities and Equipment. The Facilities, all equipment used for the manufacture of Material within the Facility[2] and activities contemplated herein, and any other facility at which any of the manufacturing or processing, packaging, labeling, testing, or storage activities related to the Material are performed will comply with all Applicable Laws and cGMP's"

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

19. Section 4.1 furhter states:

> "4.1 Quality Assurance. All Material supplied by Dishman shall meet and agreed current Specifications and shall be manufactured and stored in accordance with all Applicable Laws relevant to the Facility, Warehouse and the Quality Agreement."

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[1] "Quality Agreement" shall mean the Quality Assurance Agreement between the Parties dated January 29, 2019, and as may be further amended from time to time, and contains: the current Specifications and specifies the Parties' respective responsibilities regarding the manufacture, storage, release, quality control and quality assurance of Material in accordance with requirement of Regulatory Authorities and cGMP's. The Quality Agreement is confidential among the parties and shall be submitted under seal if and when required.

[2] "Facility" shall mean Dishman's cGMP-compliant manufacturing facilities located at 100% EOU AT survey No. 47 Paiki Sub Plot No. 1, Village Lodariyal, Taluka, Sanand, Dist. Ahmedabad – 382 220 State- Gujarat, (India) or at any other such facility of a Dishman's Affiliate as mutually agreed upon between the Parties in writing.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

20. Under the Agreement, non-conforming Material is addressed under Section 4.3 Rejection and Replacement of Material as follows:

> "4.3.1 Inspection by Noramco. …In case that Latent Defects in the Materials are notified to Dishman, Noramco agrees to give full support to Dishman for the return of the Material to its designated facility…"
>
> "4.3.2 Resolution of Disputes. …Dishman *shall* acknowledge receipt in writing to a rejection notice from Noramco within two (2) business days from the date of receipt of such rejection notice in accordance with Section 4.3.1 above … If Dishman does not agree with Noramco's determination that such Material fails to conform to the Specifications or the warranties provided by Dishman in Section 10.2, then Dishman and Noramco shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, *either party may* submit a sample of the Material to a nationally recognized testing laboratory …" (emphasis added), and
> "4.3.3 Replacement of Material. Material accepted by Dishman as not meeting the applicable requirements or the Specifications, or which is determined by the Laboratory not to meet such requirements or the Specifications, shall be returned by Noramco to Dishman, or disposed of, as directed by Dishman, at Dishman's expenses.
>
> Dishman shall replace all such rejected Material within the shortest possible time, but in any event, within a reasonable timeframe, as agree to by the Parties, after its receipts of notice of such rejection (or, *if applicable,* the Laboratory's determination that such Material was non-conforming). Without limiting any other provisions in this Agreement, Noramco may withhold payment for such shipment or the portion thereof that has been rejected by Noramco, or, if Parties cannot agree on a suitable timeframe to replace such rejected Material, *Noramco shall be entitled to a full refund* of prior payments for such shipment or the portion thereof that has been rejected by Noramco, pursuant this Section 4.3. The remedies provided by this Section 4.3 shall be the sole and exclusive remedies of Noramco in respect to any out of Specification of Material that was rejected.
>
> *The warranties given by Dishman in Section 10.2 below shall survive any failure to reject by Noramco under this Section 4.3."* (emphasis added).

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

21. On October 29, 2019, Noramco issued a Purchase Order to Dishman for the purchase of the Material.

ANSWER: Admitted.

22. At the time that Noramco issued the Purchase Order, Noramco believed that Dishman would continue to maintain an acceptable level of quality under the Agreement.

ANSWER: Defendant is without knowledge to admit or deny this allegation.

23. On February 28, 2020, the European Directorate of the Quality of Medicines & HealthCare ("EDQM") and Swissmedic conducted an inspection of the Dishman Facility.

ANSWER: Admitted.

24. Upon information and belief, as of February 28, 2020, Dishman knew that Dishman had an inspection that would result in a "critical" observation.

ANSWER: Denied as to any legal conclusions and generally denied.

25. Swissmedic issued a report of its findings from the February 28, 2020 inspection.

ANSWER: Admitted.

26. As of February 28, 2020, prior to manufacture and release of the Material, Swissmedic determined that the Dishman Facility experienced "critical deficiencies".

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Swissmedic Report speaks for itself.

27. As of February 28, 2020, prior to manufacture and release of the Material. Swissmedic determined that the deficiencies experienced at the Dishman Facility posed a risk of harm to patients.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Swissmedic Report speaks for itself.

28. As of February 28, 2020, prior to manufacture and release of the Material. Swissmedic determined that the Facility was not in compliance with GMP standards.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Swissmedic Report speaks for itself.

29. As of February 28, 2020, the Facility was not in compliance with the cGMPs requirement pursuant to Section 1.4 of the Supply Agreement.

ANSWER: Denied as to any legal conclusion, and generally denied.

30. Section 6.1 of the Supply Agreement required that Dishman notify Noramco about regulatory actions or inspections if such actions or inspections relate, directly or indirectly, to the Material.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Supply Agreement speaks for itself.

31. Dishman failed to notify Noramco of the EDQM/Swissmedic inspection in February or March of 2020.

ANSWER: Denied, Noramco was already aware of the EDQM/Swissmedic inspection in February or March 2020.

32. Dishman violated Section 6.1 of the Supply Agreement when Dishman failed to notify Noramco about the EDQM/Swissmedic regulatory inspection.

ANSWER: This allegation is a legal conclusion that requires no response.

33. The Quality Agreement required that Dishman notify Noramco about regulatory actions or inspections.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Quality Agreement speaks for itself.

34. Dishman violated the Quality Agreement when Dishman failed to notify Noramco about the EDQM/Swissmedic regulatory inspection.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the Quality Agreement speaks for itself.

35. In March 2020, after the inspection and while the Swissmedic EDQM investigation report was pending, Dishman manufactured the following Material for Noramco:

a. 60.00 Kg Olivetol, Olivetol lots No. 120 OAO0001.
b. 80.00 Kg Olivetol, Olivetol lots No. 120 OAO0002.
c. 88.20 Kg Olivetol, Olivetol lots No. 120 OAO0003.
d. 84.10 Kg Olivetol, Olivetol lots No. 120 OAO0004.
e. 82.70 Kg Olivetol, Olivetol lots No. 120 OAO0005.
f. 50.00 Kg Olivetol, Olivetol lots No. 120 OAO0006.

(collectively, the "Batches").

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

36. Dishman did not inform Noramco of the Swissmedic EDQM regulatory inspection of the Facility prior to manufacture of the Material for Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

37. On or about March 24, 2020, the batches of the Material were shipped from Dishman to Noramco.

ANSWER: Admitted.

38. Dishman did not inform Noramco of the Swissmedic EDQM regulatory inspection of the Facility prior to shipment of the Material to Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

39. Dishman did not inform Noramco that the EDQM Swissmedic inspection pertained to the Material prior to manufacture and delivery of the Material to Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

40. On or about April 14, 2020, Noramco received the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

41. On or about April 17, 2020, Dishman notified Noramco by email of the occurrence of the Swissmedic EDQM February 28, 2020 inspection of the Facility.

ANSWER: Admitted.

42. On April 18, 2020, Noramco notified Dishman of Noramco's concerns about the inspection and potential rejection of the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

43. On April 18, 2020, Noramco requested that Dishman provide Noramco with more information so that Noramco could assess the potential non-compliance involving the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

44. Pursuant to Section 6.2 of the Supply Agreement, Dishman agreed to provide Noramco with "all reasonable information and data in Dishman's possession or control reasonably necessary for Noramco (or its designees) to apply for, obtain, and maintain regulatory approvals for any Products in the United States, [and] Europe."

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

45. Pursuant to Section 6.2 of the Supply Agreement, Dishman also agreed to "reasonably cooperate" with Noramco or its designees to report information relevant to the Material to FDA and other regulatory authorities.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

46. On or about April 20. 2020, Swissmedic issued a Statement of Non-Compliance with cGMP, entitled Exchange of Information between National Competent Authorities (NCSs) of the EEA, Report No.: CH20-0177 (the "Swissmedic Report") regarding the Facility.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

47. The Swiss medic Report identified EU GMP non-compliance at the Facility.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

48. The Swissmedic Report provided as follows:

> "During the joint Swissmedic EDQM inspection1 critical, 7 major and 11 other deficiencies were identified. **The critical deficiency is related to an insufficient QA [Quality Assessment] oversight leading to a situation that constitutes a potential risk of producing products which could be harmful to the patient. The firm's approach on Materials management,** including the labelling, traceability, storage conditions, dispensing, cleaning, pest control of raw Materials, intermediates, solvents and recovered solvents

> **was considered as not in compliance with EU GMP [good manufacturing practices].** The company failed in multipurpose facility/ies to mitigate the risks of cross-contamination and was not aware of the necessary measures to be taken before introducing a new chemical entity in the sampling, dispensing and synthesis area" (emphasis added).

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

49. On or about April 24, 2020, Dishman acknowledged Noramco's request for more information and indicated that Dishman would provide a written response on April 27, 2020.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

50. Dishman failed to provide a written response on April 27, 2020.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

51. On April 28, 2020, Dishman provided an email response to Noramco's request.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

52. Dishman's April 28, 2020 response failed to include all of the information requested by Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

53. Dishman's April 28, 2020 response failed to include material assessments and Corrective and Preventative Actions ("CAPA").

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

54. On April 28, 2020, Dishman provided Noramco with a copy of the Swissmedic Report.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

55. Upon information and belief, as a result of EDQM/Swissmedic inspection, 9 Certificates of Suitability to the monographs of the European Pharmacopoeia were suspended.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

56. As a result of the EDQM/Swissmedic inspection Dishman was prohibited from distributing the Materials.

ANSWER: Denied as to any legal conclusions. As to factual allegations, denied.

57. The critical observation was issued by Swissmedic and EDQM due to conditions which violate ICH Q7.

ANSWER: Denied as to any legal conclusions. As to factual allegations, denied.

58. Per the Swissmedic report, non-compliant manufacturing operations were observed at the Facility for the manufacture of active substances (i.e. Active Pharmaceutical Ingredients or "APIs").

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

59. Olivetol is a regulatory starting Material for APIs.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

60. Swissmedic classified the issues as a "*critical*" observation with the potential to be harmful to patients.

ANSWER: Denied as to any legal conclusions. As to factual allegations, the document speaks for itself.

61. A "critical" deficiency indicates that a deficiency was determined which was produced or leads to a significant risk of producing or distributing a product which is harmful to the human patient.

ANSWER: Denied as to any legal conclusions, and generally denied.

62. A "critical" deficiency may also involve a suspicion that the manufacturer or distributor may be involved in fraudulent activities, misrepresentation of facts or the counterfeiting of products or data.

ANSWER: Denied as to any legal conclusions and generally denied.

63. A "critical" deficiency may indicate that a deficiency was determined as a result of a combination of several "major" deficiencies, none of which on their own may be critical, but which may together represent a critical deficiency or indicate a failure of the quality systems.

ANSWER: Denied as to any legal conclusions and generally denied.

64. The Swissmedic EDQM inspection revealed that the manufacturing procedures at the Facility were subject to a "critical" observation.

ANSWER: Denied as to any legal conclusions, and generally denied.

65. On May 26 and 28, 2020, Dishman sent a written assessment to Noramco for the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

66. The Dishman risk assessment and audit report indicated that the Material was manufactured in the same area of the Facility as the deficiency outlined in the Swissmedic report, area 3C.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

67. Dishman's assessment failed to identify potential failure modes related to the Swissmedic EDQM observations.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

68. Dishman's assessment failed to identify the severity, likelihood, or detectability of the failure for the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

69. Noramco requested a meeting to discuss the written assessment.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

70. Noramco and Dishman scheduled a meeting for June 3, 2020.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

71. Dishman later requested that the meeting be rescheduled to June 15, 2020.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

72. On June 15, 2020, a meeting between the parties was held.

ANSWER: Admitted.

73. At the June 15th meeting, Noramco asked Dishman for additional information required for Noramco to complete its analysis of the GMP status of the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

74. Noramco requested that Dishman provide additional information regarding the Material assessment, risk assessment, CAPA updates, and for detailed information regarding cleaning procedures and the site master file.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

75. On July 6, 2020, Dishman provided only an updated Site Master File and a high-level cleaning policy.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

76. Dishman never provided Noramco with formal risk assessments for the Olivetol.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

77. Dishman has failed to provide the requested information regarding risk assessment and CAPAs.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

78. Noramco then performed internal analysis based on the information provided by Dishman to determine whether the Material was cGMP compliant and could be accepted by Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

79. Noramco had no lawful option other than to reject the Material for failure to comply with cGMP requirements.

ANSWER: Denied as to legal conclusions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remainder of this allegation.

80. Noramco had no lawful option other than to reject the Material for having been manufactured in a non-cGMP compliant Facility.

ANSWER: Denied as to legal conclusions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remainder of this allegation.

81. Noramco had no lawful option but to reject the Material due to the following latent defects:

a. Noramco's discovery of Dishman's failure to comply with ICH Q7 as required in the Supply Agreement;

b. Noramco's discovery that systemic failures existed at the Facility which constitute a potential risk of producing products which could be harmful to patients;

c. Dishman's failure to provide information to Noramco prevented Noramco from conclusively determining that the conditions observed by Swissmedic / EDQM did not present a risk of cGMP non-compliance to the Material.

ANSWER: Denied as to legal conclusions and generally denied.

82. A recipient of knowingly adulterated pharmaceutical material which allows such material to enter the stream of commerce may face criminal and civil charges for knowingly manufacturing adulterated pharmaceutical products and endangering public health.

ANSWER: Denied as to legal conclusions and generally denied.

83. The latent defect of the Material cannot be cured or tested but is deemed "adulterated" in accordance with cGMP and the Feed, Drug, and Cosmetic Act:

> A drug or device shall be deemed to be adulterated-if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice [cGMP] to assjure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. 351 (a)(2)(B).

ANSWER: Denied as to legal conclusions and generally denied.

84. Dishman failed to rebut the unresolved risk of "adulteration" of the Material and such risk could be passed to a patient.

ANSWER: Denied as to legal conclusions and generally denied.

85. In accordance with cGMP, no efforts to cure are available to Dishman because the Material was manufactured under non-cGMP conditions, regardless of futher testing or evaluation.

ANSWER: Denied as to legal conclusions and generally denied.

86. Optional laboratory testing contemplated under the Supply Agreement would be futile because the material is deemed "adulterated" by the applicable law and regulations.

ANSWER: Denied as to legal conclusions and generally denied.

87. Once material is deemed adulterated because of failure of the manufacturer to comply with cGMP in its plant, testing is irrelevant.

ANSWER: Denied as to legal conclusions and generally denied.

88. Accordingly, Noramco was obligated to assess the risk and take mitigating actions under the law.

ANSWER: Denied as to legal conclusions and generally denied.

89. As provided under the Agreement, Noramco had the right to reject any non-conforming product and demand recall of same.

ANSWER: Denied as to legal conclusions and generally denied.

90. On or about August 11, 2020, Noramco requested that Dishman return the Material.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

91. On August 19, 2020, Noramco notified Dishman in writing, that the Material, Olivetol lots 120OAO001, 120OAO002, 120OAO003, 120OAO004, 120OAO005, and 120OAO006 (collectively the "Non-conforming Olivetol" or the "Rejected Material") did not comply with the terms of the Supply Agreement and pursuant to the Swissmedic report were unacceptable for cGMP use and must be collected for return by Dishman.

ANSWER: Denied as to legal conclusions and generally denied.

92. Noramco requested that Dishman coordinate the return of these Rejected Materials and provide a full refund for the purchase price paid.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

93. On August 28, 2020, Dishman responded and asked for a call to discuss.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

94. From September 2020 to January, 2021, the Parties corresponded regarding the disposition and return of the Olivetol to Dishman.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

95. On September 1, 2020, the Parties held a meeting to discuss the return of the Olivetol.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

96. On September 24, 2020, Dishman agreed to return the Olivetol and to organize its return to Dishman. **Exhibit B**.

ANSWER: Denied. The document speaks for itself.

97. On October 6, 2020, Dishman wrote to Noramco, and Dishman agreed in writing to provide a full refund to Noramco over time. **Exhibit B.**

ANSWER: Denied. The document speaks for itself.

98. On October 6, 2020, Dishman agreed to make a 70% payment of the refund during the fourth quarter of 2020 and 30% payment of the refund during second quarter of 2021. **Exhibit B.**

ANSWER: Denied. The document speaks for itself.

99. On December 9, 2020, Noramco issued a statement to Dishman confirming that the Material had been stored in accordance with cGMP requirements as per ICH Q7, labelled storage requirements, and Noramco's procedures.

ANSWER: Admitted as to statement being issued. Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

100. On January 6, 2021, Noramco followed-up with Dishman regarding the pickup of the Non-Conforming Olivetol. **Exhibit B.**

ANSWER: Denied. The document speaks for itself.

101. On January 14, 2021, Dishman re-confirmed its agreement to take the Rejected Material back and informed that Dishman's CEO was coordinating the return. **Exhibit B.**

ANSWER: Denied. The document speaks for itself.

102. Based on the foregoing agreement, Noramco refrained from legal action.

ANSWER: Denied as to legal conclusions and generally denied.

103. Despite Noramco's demand, Dishman has failed to adhere to its agreement to accept return of the Rejected Material, to pick up the Rejected Material, and provide a refund to Noramco.

ANSWER: Denied as to legal conclusions and generally denied.

104. As of this date, Dishman has neither picked up the Rejected Material nor refunded the purchase price to Noramco in the amount of $600,500.00.

ANSWER: Denied as to legal conclusions, otherwise admitted.

105. Dishman's delay in organizing return and refund of the Rejected Material has resulted in extended usage of Noramco's storage facilities.

ANSWER: Denied as to legal conclusions and generally denied.

106. Dishman's failure to pick up the Rejected Material creates substantial costs at about $2000 per month for Noramco to store the Material consistent with standard cGMP requirements.

ANSWER: Denied as to legal conclusions and generally denied.

107. On August 31, 2021, Noramco issued a letter to Dishman demanding that Dishman organize the pickup and collection of the Rejected Material and issue a refund of 100% of the purchase price to Noramco.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of this allegation.

108. Demand has been made for full payment by the Defendant; however, no payment has been made.

ANSWER: Denied as to legal conclusions, otherwise admitted.

109. Defendant owes a total amount due of $600,500.00 plus ongoing storage costs, per diem interest and costs.

ANSWER: Denied as to legal conclusions and generally denied.

FIRST COUNT
(Breach of Contract)

110. Plaintiff repeats and realleges all of the allegations contained in the paragraphs 1 through 109 of the Complaint as though set forth at length herein.

ANSWER: Defendant repeats its responses to the paragraphs above.

111. Noramco has made payment of $600,500.00 for the Material at issue.

ANSWER: Admitted.

112. The Supply Agreement provides that all Material supplied by Dishman shall be manufactured at a cGMP compliant facility, and stored in accordance with all Applicable Laws relevant to the Facility, Warehouse, and Quality Agreement.

ANSWER: Denied as to legal conclusions and generally denied.

113. cGMP requirements are laws applicable to the Facility.

ANSWER: Denied as to legal conclusions and generally denied.

114. The Agreement further requires Dishman to notify Noramco about regulatory actions or inspections if such actions or inspections address, directly or indirectly, the supply of Material.

ANSWER: Denied as to legal conclusions and generally denied.

115. The Quality Agreement entered into between the parties also requires notice to Noramco of actions or inspections affecting the Facility or the Material.

ANSWER: Denied as to legal conclusions and generally denied.

116. In breach of the Agreement, Dishman failed to manufacture the Material at a cGMP compliant facility, in accordance with applicable laws and the Quality Agreement, failed to inform Noramco of the relevant regulatory inspection, failed to refund and process return of the Rejected Material and caused Noramco to incur substantial costs for storage of $2000 per month.

ANSWER: Denied as to legal conclusions and generally denied.

117. The Supply Agreement provides that Material recognized by the parties as not meeting the applicable requirements shall be returned by Noramco to Dishman, or disposed or, as directed by Dishman, at Dishman's expense.

ANSWER: Denied as to legal conclusions and generally denied.

118. Because Dishman's Material is not cGMP compliant, and Dishman cannot cure or replace the Rejected Material. Noramco is entitled to a full refund of all prior payments for the Rejected Material pursuant to Section 4.3 of the Agreement.

ANSWER: Denied as to legal conclusions and generally denied.

WHEREFORE, Judgment is demanded for return of the Rejected Material at Dishman's expense, in addition of monetary judgment in the sum of **$600,500.00**, together with storage costs, lawful interest, costs of cover, costs of suit, and for such other relief deemed by the Court to be equitable and just, as provided by law.

ANSWER: Denied as to legal conclusions and generally denied.

SECOND COUNT
(Breach of Express Warranty)

119. Plaintiff repeats and realleges all of the allegations contained in the paragraphs 1 through 118 of the Complaint as though set forth in length herein.

ANSWER: Defendant repeats its responses to the paragraphs above.

120. In connection with the sale of the Material at issue, Dishman expressly warranted under Section 10.2 Dishman Warranties:

> "Section 10.2.1 Material. All Material supplied hereunder shall (a) comply with all Applicable Laws and the Quality Agreement and meet all Specifications and cGMP's [current good manufacturing practices], and (b) Dishman shall perform and document all manufacturing and supply activities contemplated herein compliance with all Applicable Laws."

> "Section 10.2.2 Facilities and Equipment. The Facilities, all equipment used for the manufacture of Material within the Facility and activities contemplated herein, and any other facility at which any of the manufacturing or processing, packaging, labeling, testing, or storage activities relating to the Material are performed will comply with all Applicable Laws and cGMP's."

ANSWER: Denied as to legal conclusions and generally denied.

121. Dishman breached this express warranty in that it failed to comply with applicable laws and cGMP regulatory requirements.

ANSWER: Denied as to legal conclusions and generally denied.

122. Noramco notified Dishman of the nonconformities in the Material on August 19, 2020, which was during the pendency of the parties' direct discussions, and a reasonable time after Noramco discovered the breach and could ascertain the latent defect.

ANSWER: Denied as to legal conclusions and generally denied.

123. The Material at issue does not conform to the Specification requirements defined in the Quality Agreement.

ANSWER: Denied as to legal conclusions and generally denied.

124. The Material was rejected due to Dishman's failure to comply with mandatory cGMP and applicable laws under the Supply Agreement.

ANSWER: Denied as to legal conclusions and generally denied.

125. The Supply Agreement Section 4.3.3 specifically provides that "The *warranties* given by Dishman in Section 10.2 below *shall survive* any failure to reject by Noramco under this Section 4.3."

ANSWER: Denied as to legal conclusions and generally denied.

126. Dishman failed to meet the regulatory compliance requirements, as evidenced by the outcome of the EDQM/Swissmedic inspection and the Swissmedic Statement of Non-Compliance with GMP.

ANSWER: Denied as to legal conclusions and generally denied.

127. Thus, Dishman breached its warranty that all equipment used for the manufacture of Material within the Facility and activities contemplated under Supply Agreement, were to be performed in compliance with all Applicable Laws and cGMP's.

ANSWER: Denied as to legal conclusions and generally denied.

128. As a result of Dishman's breach of express warranty, Noramco has suffered damages in an amount not less than **$600,500.00**, which represents Noramco's costs paid for the defective materials.

ANSWER: Denied as to legal conclusions and generally denied.

129. Dishman's breach also caused the following damages to Noramco storage costs of $2000/month, per diem interest, litigation costs and attorney fees.

ANSWER: Denied as to legal conclusions and generally denied.

130. In the event that Dishman is unable or continually unwilling to retrieve the delivered Materials, Noramco will also bear destruction costs at an amount to be ascertained at the time of trial.

ANSWER: Denied as to legal conclusions and generally denied.

WHEREFORE, Judgment is demanded for collection of the Rejected Material at Dishman's expense, in addition of monetary judgment of the sum of

$600,500.00, together with storage costs, lawful interest, costs of cover, costs of destruction of the nonconforming Material, attorneys' fees, costs of suit, and for such other relief deemed by the Court to be equitable and just, as provided by law.

ANSWER: Denied as to legal conclusions and generally denied.

THIRD COUNT
(Unjust Enrichment)

131. Plaintiff repeats and realleges all of the allegations contained in the paragraphs 1 through 130 of the Complaint as though set forth at length herein.

ANSWER: Defendant repeats its responses to the paragraphs above.

132. At the times mentioned herein, by accepting payment of $600,500.00 from Noramco and failing to deliver conforming Material in accordance with cGMP requirements, Dishman received the unfair benefit of the payment of **$600,500.00** without exercising the obligations and services required of Dishman pursuant to the parties' Agreement. Denied as to legal conclusions and generally denied.

ANSWER: Denied as to legal conclusions and generally denied.

133. Despite repeated demand, Dishman has failed to tender a refund to Noramco for the Non-Conforming Material. Dishman continues to retain the benefits of such sums paid, and burdens Noramco with continuing safekeeping and storage of the Rejected Material at the cost of **$2000 per month.**

ANSWER: Denied as to legal conclusions and generally denied.

WHEREFORE, Judgment is demanded for return of the Rejected Material at Dishman's expense, in addition of monetary judgement of the sum of **$600,500.00**, together with storage costs, incidental damages, consequential damages, lawful

interest, attorney's fees, costs of cover, costs of suit and for such other relief deemed by the Court to be equitable and just, as provided by law.

ANSWER: Denied as to legal conclusions and generally denied.

JURY DEMAND

Dishman demands a trial by jury as to all issues so triable.

AFFIRMATIVE DEFENSES

A. The Complaint fails to state a claim upon which relief can be granted.

B. Plaintiff's claims are barred by the principles of Latches, Waiver, Unclean Hands and/or Estoppel for the reasons detailed in Defendants Opening Brief in Support of its Motion to Dismiss –specifically, Noramco failed to follow the notice, testing and rejection procedures set forth in the Supply Agreement. (*See* D.I. 7.)

C. Plaintiff's claims are barred because there was No Beach by Defendant.

D. Plaintiff's claims are barred because of a Lack of Privity.

E. Plaintiff's claims are barred because of the Statute of Frauds.

F. Plaintiff's claims are barred because of the Parol Evidence Rule.

G. Plaintiff's claims are barred because of Improper Notice of Alleged Breach.

H. Plaintiff's damages are barred because of Substantial Performance.

I. Plaintiff's damages are barred because of its Failure to Mitigate.

Dated: April 28, 2022

Respectfully submitted,

STAMOULIS & WEINBLATT LLC

/s/Stamatios Stamoulis

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Attorney for Defendant Dishman USA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2022, I electronically filed the above document(s) with the Clerk of Court using CM/ECF, which will send electronic notification of such filings to all registered counsel.

/s/ Stamatios Stamoulis
Stamatios Stamoulis (#4606)